ThermoFisher
SCIENTIFIC

K110035

510(k) SUMMARY
(As required by section 21 CFR 807.92(c))

JUN 28 2011

Contact: Thermo Fisher Scientific Oy
Ratastie 2
01620 Vantaa
Finland
Contact person: Päivi Sormunen
Director, Operations and QRC
Telephone: +358-9-32910762
Fax: +358-9-32910300
Email: paivi.sormunen@thermofisher.com

Date Prepared: June 09, 2011

Manufacturer: Thermo Fisher Scientific Oy
Ratastie 2
01620 Vantaa
Finland

Establishment registration: 9610942

Product Trade Name:	Indiko Glucose (HK)
Common/Usual Name:	Clinical chemistry analyzer Glucose hexokinase assay
Classification Name:	Discrete photometric chemistry analyzer for clinical chemistry (21 CFR § 862.2160, Product code JJE) Glucose test system (21 CFR § 862.1345 Glucose(HK), Product code CFR)
Predicate device:	DPC T60i Clinical Chemistry Analyzer (=Konelab 60i analyzer), k061107 Glucose(HK), k061107

Device description:

The Indiko is automated random access discrete photometric analyzer, capable of performing up to 30 photometric tests.

The sample disk has an integrated barcode reader which allows cup/tube recognition. The barcode reader can read the following codes: code 128, USS Codabar, interleaved 2 of 5 and code 39 with check digit.

Reaction cells are discrete disposable (single use) multicell cuvettes with 10 reaction measurement cells in a row. On-board capacity of 36 multicell cuvettes (equal to 360 reaction cells), with continuous loading capability, typically 2 hours walk-away time. The quality of the reaction cells is checked at the start of the routine work automatically. The measurements are performed at 37°C.

The analyzer incorporates robotics, computer, and communication technology to render simple and reliable long-term operation. The operating system works with Windows® 7. The user interface software is graphical. The data input can be done online or by touch screen or mouse or keyboard.

Reagents are liquid, the reagent bottles are placed on the reagent/sample disk, which holds maximum 30 positions, the reagent/sample disk is cooled 10°C below ambient temperature.

Statement of Intended Use

The Thermo Scientific Indiko Clinical Chemistry Analyzer is a fully automated random access analyzer used to measure a variety of analytes that may be adaptable to the analyzer depending on the reagent used.

The Indiko Glucose (HK) test system, is intended for *in vitro* diagnostic use in the quantitative determination of the glucose concentration in human plasma on the Indiko analyzer.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Summary of Technological Characteristics in Comparison to the Predicate Device:

Similarities

Attribute	Device	Predicate
Reagents	Same	Same
Analyzer		
• Discrete Photometric Analyzer	Same	Same
• Software Driven	Same	Same
• For clinical laboratory professionals	Same	Same
• Automated dilutions	Same	Same
• Sample reruns	Same	Same

Differences

Attribute	Device	Predicate
Reagents Testing Process		
• Clot detection	No	Yes
• ISE testing	Not included	Direct
Analyzer	Indiko benchtop	DPC T60i KUSTI=Konelab 60i, stand alone

Summary of non-clinical testing

Design verification and validation testing was performed to ensure that the design specifications and customer requirements were met. A method comparison study was performed to compare the new device to the predicate device to support a determination of substantial equivalence. Below is a summary of performance testing results:

Performance Characteristics **Glucose (HK)**			
Performance experiment	**Result**	**Acceptance criteria**	**Performance accepted**
Method comparison Indiko Clinical Chemistry Analyzer vs. DPC T60 (Konelab 60i)	y = 1.01 x + 0.7 r = 1 n = 117 Range: 6 – 700 mg/dl	Y=ax+b, where a=1.00 ± 0.03 b=0.00 ± 3.6 mg/dl r ≥ 0.97 max bias at 90 mg/dl 5%	Yes
Precision Within run (Repeatability)	Low: CV 0.7 % Middle: CV 0.6 % High: CV 0.8 %	Low: CV 2.0 % Middle: CV 2.0 % High: CV 1.8 %	Yes
Precision Between run	Low: CV 0.8 % Middle: CV 1.2 % High: CV 0.6 %	Not specified	Yes
Precision Total (Within Device)	Low: CV 1.6 % Middle: CV 1.5 % High: CV 1.5 %	Low: CV 3.5 %, Middle: CV 3.5 %, High: CV 3.0 %	Yes
Linearity/ Measuring range	Measuring range: 5 – 720 mg/dl	Measuring range: 5 - 720 mg/dl Maximum bias from the estimated straight line ± 2.7 mg/dl or ± 5 %.	Yes
Limit of Blank (LoB), Limit of Quantitation (LoQ)	LoB: 0.18 mg/dl LoQ: 0.54 mg/dl	LoB: < 5.4 mg/dl LoQ: < 9.0 mg/dl	Yes
Interference Hemolysate	No interference found up to 1000 mg/dl of hemoglobin.	No interference found up to 500 mg/dl. Recovery within ± 5 % of initial value.	Yes
Interference Bilirubin (unconjugated)	No interference found up to 50 mg/dl conjugated bilirubin.	No interference found up to 23 mg/dl. Recovery within ± 5 % of initial value.	Yes
Interference Bilirubin (conjugated)	No interference found up to 47 mg/dl conjugated bilirubin.	No interference found up to 23 mg/dl. Recovery within ± 5 % of initial value.	Yes
Interference Lipemia	No interference found up to 1000 mg/dl of Intralipid®.	No interference found up to 500 mg/dl. Recovery within ± 5 % of initial value.	Yes

Summary of Clinical testing

No additional clinical evaluations of the devices for use have been conducted.

Conclusion

The Indiko clinical chemistry analyzer and Glucose (HK) reagent kit are substantially equivalent to DPC T60i clinical chemistry analyzer and Glucose (HK) kit respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUN 28 2011

Thermo Fisher Scientific Oy
c/o Ms. Päivi Sormunen
Director of Operations and Quality,
Regulatory and Compliance
CDD Finland
Ratastie 2
Vantaa, 01620 Finland

Re: k110035
Trade/Device Name: Indiko Clinical Chemistry Analyzer, Indiko Glucose (HK)
Regulation Number: 21 CFR 862. 1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR, JJE
Dated: June 15, 2011
Received: June 15, 2011

Dear Ms. Sormunen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **k110035**

Device Name: **Indiko Clinical Chemistry Analyzer**
Indiko Glucose(HK)

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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